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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,341	10/25/2001	Bradley Stuart Galer	1203-01	3845

7590

06/03/2003

IP Department
Schnader Harrison Segal & Lewis
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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/03/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,341

Applicant(s)

GALER, BRADLEY STUART

Examiner

Simon J. Oh

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 8-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment, petition for extension of time under 37 C.F.R. 1.1369(a), request for withdrawal of a non-publication request, and the petition for revival of an application for a patent abandoned unintentionally under 37 C.F.R. 1.137(b). All were received on 13 March 2003. The notice for acceptance of a publication request was entered into the instant application on 25 March 2003. The petition to revive the instant non-provisional application under the unintentional provisions of 37 C.F.R. 1.137(f) was granted and entered into the case file on 25 March 2003.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 10 under 35 U.S.C. 112, second paragraph is withdrawn with the amendment of that claim.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3, 6, 8, 9, 11, and 12 under 35 U.S.C. 102(b) as being clearly anticipated by Hind is maintained.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 3, 6, 8, 9, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable over Hind is maintained.

The rejection of Claim 10 under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Botknecht *et al.* is hereby withdrawn.

Claims 1, 3, and 8-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Hind in view of Rolf *et al.* (U.S. Patent No. 5,741,510)

The Hind patent teaches methods and compositions for reducing pain from shingles by topical administration of lidocaine at a dosage below that which achieves analgesia without inducing anesthesia or systemic side effects (See Column 3, Lines 1-17 and 29-36). In the disclosed compositions, lidocaine is present in amounts of about 1 to 25% by weight (See Column 3, Lines 55-65). Included in the disclosure are details of a study in which patches containing 5% lidocaine as well as other excipients are administered to patients (See Column 15, Lines 11-18).

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Hind does not indicate that the disclosed compositions and methods can be used to treat pain from the group consisting of myofascial pains, fibromyalgia, bursitis, costochondritis, repetitive motion injuries, carpal tunnel syndrome, and nociceptive pain.

The Rolf *et al.* patent teaches an analgesic adhesive patch that can be used to treat arthritis, backache, muscular aches, and strains. Lidocaine is listed among the active ingredients suitable for use in the disclosed patch (See Claims 1 and 3).

It would be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hind and Botknecht *et al.* into the objects of the instant application. The teachings of Hind provide for topical compositions comprising lidocaine and methods to treat pain in a way that produces analgesia without causing anesthesia. The teachings of Rolf *et al.* disclose that, in one embodiment, an analgesic patch comprising lidocaine can be used in the treatment of pain caused by arthritis, backache, muscular aches, and strains, which are all known to be various type of nociceptive pain. In contrast to other cited prior art references of record, the compositions of Rolf *et al.* do not require a combination of active ingredients in order to effect treatment. It is the position of the examiner that one of ordinary skill in the art, at the time the claimed invention was made, would be observe the structural similarity of the compositions disclosed in the prior art references, and would thus be motivated to use the compositions and methods of treatment of Hind to relieve pain stemming from the conditions described in Rolf *et al.* One of ordinary skill in the art would have a reasonable expectation of success that the compositions and methods of the combined disclosure of the prior art would allow for the use a patch comprising lidocaine in a concentration that induces analgesia, rather than anesthesia, for the treatment of both nociceptive pain and neuropathic pain.

Thus, the claimed invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 13 March 2003 have been fully considered but they are not found to be entirely persuasive. The applicant has not distinguished a structural difference in the instantly disclosed methods and compositions. Therefore, it is the position of the examiner that the capability of the methods and compositions disclosed in Hind *et al.* to treat non-neuropathic pain would be inherent to the disclosure of Hind *et al.* The range of active ingredient in the disclosed compositions encompasses the range claimed by the applicant, and the applicant has distinguished no substantial difference in the method of treatment, that is, the administration of a patch containing a particular amount of lidocaine. Therefore, as the prior art teaches the same procedure of administering the same composition, it is the position of the examiner that one of ordinary skill in the art would expect the same result in the treatment of pain, whether it is neuropathic or not. As such, the rejection of Claims 1, 3, 6, 8, 9, 11, and 12 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) is deemed proper and is maintained.

Presently, the examiner also rejects all currently pending claims under 35 U.S.C. 103(a) over Hind in view of Rolf *et al.* The Rolf *et al.* patent, unlike the Botknecht *et al.* patent, does not require a combination of active ingredients in order to effect treatment of various types of nociceptive pain, such as arthritis, backache, muscular aches, and strains. As such, the examiner cannot find the instantly claimed invention patentable over the prior art.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjoh
May 21, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600